

PHARMACARE NEWSLETTER

Page #1

April 19, 2002
02-03

Web site: <http://www.healthservices.gov.bc.ca/pharme/index.html>

PLEASE CIRCULATE AMONG DISPENSING STAFF

Special Authority Coverage for Infliximab and Etanercept

Treatment of severe, active rheumatoid arthritis

Effective **April 22, 2002**, infliximab and etanercept will be available for coverage under the Pharmacare Special Authority (SA) process when prescribed to treat severely active rheumatoid arthritis in adults.

Treatment of severe, active Crohn's Disease and Fistulizing Crohn's Disease

Effective **April 22, 2002**, infliximab will be available for coverage under the SA process when prescribed to treat severe, active Crohn's Disease or Fistulizing Crohn's Disease in adults. Please note that etanercept is not available for this indication.

Criteria for coverage

For all the above-mentioned indications, only Special Authority Requests submitted by the prescribing rheumatologist or gastroenterologist will be considered. The prescribing rheumatologist or gastroenterologist must submit Special Authority requests for all patients, including those currently being treated with infliximab or etanercept, and all patients must meet criteria specific to the medication requested and the indication for its use. The criteria for coverage are detailed in the following pages.

Patients who meet the criteria will be approved for an initial period of coverage. At a specified point in treatment (refer to the specific criteria for details), the rheumatologist or gastroenterologist must reassess the patient and submit a copy of the assessment to Pharmacare. An expert Advisory Committee will review assessments to determine whether continued coverage is appropriate.

Units of measure to be used

When submitting claims for infliximab and etanercept on PharmaNet, please specify the quantity using the appropriate unit of measure, as indicated below:

Infliximab	DIN 2244016	number of vials
Etanercept	DIN 2242903	number of kits



BRITISH
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Ministry of Health Services
Pharmacare

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Infliximab/Etanercept – Initial Coverage for Rheumatoid Arthritis

Criteria for initial coverage

Patients must meet all criteria. To qualify for continuing coverage, patient must be reassessed at the 8th to 12th week of treatment.

- ☐ To be used in combination with methotrexate for the reduction in signs & symptoms of severely active rheumatoid arthritis in adult patients
 - ☐ Prescribed by a rheumatologist
 - ☐ Patient is refractory to:
 - 1) ☐ methotrexate weekly parenteral (sc or im) therapy at 25mg or greater (15mg or greater if patient is 65 years of age or over) for more than 8 weeks.
 - PLUS
 - 2) ☐ gold weekly injections for 20 weeks or
 - ☐ sulfasalazine at least 2gm daily for 3 months or
 - ☐ azathioprine 3mg/kg/day for 3 months
 - PLUS
 - 3) ☐ leflunomide 20mg daily for 10 weeks (not a requirement for patients who began infliximab/etanercept therapy prior to June 2001)
 - PLUS
 - 4) one of the following combinations:
 - ☐ methotrexate with cyclosporin (minimum 4 month trial on both or intolerance) or
 - ☐ methotrexate with hydroxychloroquine **and** sulfasalazine (minimum 4 month trial on triple therapy or intolerance) or
 - ☐ methotrexate with gold
- or, for etanercept special authorities only,**
- in patients who are intolerant or who have contraindications to methotrexate therapy, refractory to a combination of at least two of the following drugs:
- ☐ gold ☐ cyclosporin ☐ leflunomide ☐ sulfasalazine

Refractory defined as one or more of the following:

- ☐ lack of effect at doses and for duration specified above
- ☐ intolerable side-effects (specify side-effect at dose and duration of treatment)
- ☐ contraindications to therapy as defined in product monographs (please specify)

Contraindications (if any of the listed contraindications exist, patient is ineligible for coverage):

Infliximab	Y ☐ N ☐	Severe infection (such as sepsis, abscesses, tuberculosis and opportunistic infections)
	Y ☐ N ☐	Hypersensitivity to infliximab
	Y ☐ N ☐	Pregnancy/lactation
Etanercept	Y ☐ N ☐	Patient with, or at risk of, sepsis syndrome
	Y ☐ N ☐	Active infection(s)
	Y ☐ N ☐	Hypersensitivity to etanercept

Criteria for coverage beyond twelve weeks

- ☐ Prescribed by a rheumatologist
- ☐ Patient has been assessed after the eighth to twelfth week of anti-TNF therapy to determine response to treatment and meets the following response criteria:
 - ☐ greater than 20% reduction in the number of tender and the number of swollen joints **PLUS**
 - ☐ greater than 20% improvement in the physician global assessment scale **PLUS EITHER**
 - ☐ greater than 20% improvement in the patient global assessment scale. **OR**
 - ☐ greater than 20% reduction in the acute phase as measured by ESR or CRP

Criteria for continued coverage beyond one year

- ☐ Patient has been assessed after one year of treatment by the prescribing rheumatologist and a copy of the assessment report is attached for review by the Rheumatoid Arthritis Drug Benefit Adjudication Advisory Committee

Infliximab – Coverage for Severe, Active Crohn's Disease

Criteria for initial coverage

Patients must meet ALL the criteria.

Initial approval is for a single dose of 5 mg/kg/dose. For continuing coverage, patient must be reassessed after initial dose. For patients with fistulizing Crohn's Disease, please refer to page 4.

- ☐ Infliximab is being prescribed by a gastroenterologist.
- ☐ Patient is an adult and has severe, active Crohn's disease
- ☐ Patient is refractory to:
 - 1) 5 ASA products (minimum trial of 3 grams per day for 6 weeks). Specify drug/dose/duration of therapy
PLUS
 - 2) Glucocorticoids
 - ☐ Inadequate response to initial therapy with high dose such as prednisone 40 mg per day for at least 2 weeks (specify drug, dose and duration)
 - OR**
 - ☐ Treatment discontinued due to serious adverse reactions (specify reaction, drug, dose and duration of treatment)
 - OR**
 - ☐ Contraindication to therapy (specify)**PLUS**
 - 3) Immunosuppressive therapy (specify reaction, drug, dose and duration of treatment).
 - ☐ azathioprine 2 to 2.5mg/kg/day for a minimum of 3 months **or** treatment discontinued at less than 3 months due to serious adverse reactions
 - OR**
 - ☐ 6-mercaptopurine 50 to 70mg/day for a minimum of 3 months **or** treatment discontinued at less than 3 months due to serious adverse reactions
 - OR**
 - ☐ methotrexate 15 to 25mg/week for a minimum of 3 months **or** treatment discontinued at less than 3 months due to serious adverse reactions

B. CONTRAINDICATIONS (if any listed contraindication exists, patient is ineligible for coverage):

- Y ☐ N ☐ Severe infection (such as sepsis, abscesses, tuberculosis and opportunistic infections)
- Y ☐ N ☐ Hypersensitivity to infliximab
- Y ☐ N ☐ Pregnancy/lactation

Criteria for continued coverage after initial dose

- ☐ Patient has been assessed by prescribing gastroenterologist after initial dose and a copy of the assessment report is attached for review by the Crohn's Disease Drug Benefit Adjudication Advisory Committee.

Infliximab – Coverage for Fistulizing Crohn's Disease

Criteria for initial coverage

Patients must meet ALL the criteria.

The initial coverage will allow for 3 doses of 5mg/kg/dose, administered at 0, 2 and 6 weeks. For continuing coverage, patient must be reassessed after the initial doses. For patients with non-fistulizing Crohn's Disease, see page 3.

- ☐ Infliximab is being prescribed by a gastroenterologist.
- ☐ Patient is an adult with actively draining perianal or enterocutaneous fistula(e) that have recurred or persisted despite:

- 1) Course of appropriate antibiotic therapy (e.g., ciprofloxacin with or without metronidazole for a minimum of 3 weeks). Specify drug/dose/duration of therapy.

PLUS

- 2) Immunosuppressive therapy:

- ☐ azathioprine 2 to 2.5mg/kg/day for a minimum of 6 weeks or treatment discontinued at less than 6 weeks due to serious adverse reactions (specify reaction, drug, dose and duration of treatment)

OR

- ☐ 6-mercaptopurine 50 to 70mg/day for a minimum of 6 weeks or treatment discontinued at less than 6 weeks due to serious adverse reactions (specify reaction, drug, dose and duration of treatment)

OR

- ☐ methotrexate 15 to 25mg/week for a minimum of 6 weeks or treatment discontinued at less than 6 weeks due to serious adverse reactions (specify reaction, drug, dose and duration of treatment)

CONTRAINDICATIONS (if any listed contraindication exists, patient is ineligible for coverage):

- Y ☐ N ☐ Severe infection (such as sepsis, abscesses, tuberculosis and opportunistic infections)
- Y ☐ N ☐ Hypersensitivity to infliximab
- Y ☐ N ☐ Pregnancy/lactation

Criteria for continued coverage beyond one year

- ☐ Patient has been assessed by prescribing gastroenterologist after initial doses and a copy of the assessment report is attached for review by the Crohn's Disease Drug Benefit Adjudication Advisory Committee.

